Protocol of biorevitalization with Sodium Hyaluronate 45mg/3mL

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INTRODUCTION

Application of dermal implants for biorevitalization containing Hyaluronic Acid (HA) corrects the signs of skin aging and dermal atrophy by restoring hydration and normal skin physiology.
Depending on the degree of skin photoaging and its condition, HA can provide satisfactory results both as a single treatment and/or as one of the stages of a treatment.
The objective of the study is to evaluate the efficacy achieved in the improvement of patients with various degrees of skin photoaging, as well as to evaluate their degree of satisfaction during the international multicenter study with 51 patients involved.

ACTIVE AGENTS

3 ml pre-filled syringe with non-cross-linked HA (concentration of 15 mg/ ml) .

INJECTION TECHNIQUE

Injection with a 30G or 32G needle and a luer lock syringe, leaving papules on the skin resting on the retention ligaments.
Volume per session: 1.5 ml side / 3.0 ml for the full face.

PROTOCOL

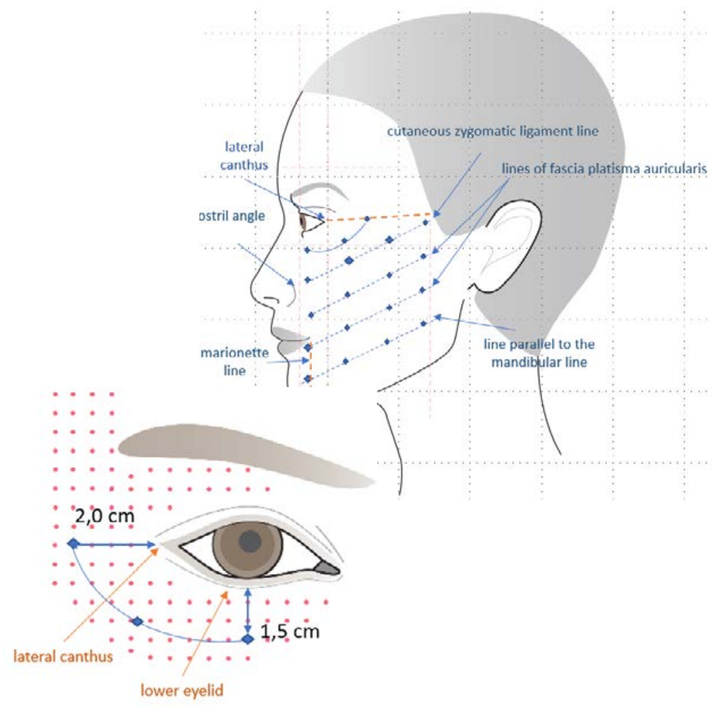
Day 0. Treatment 1.
1. Selection of the patient according to the general condition of the skin.
2. Examination of the skin according to certain parameters (texture, thickness, skin type, turgor, flaccidity, general condition).
3. Selection of the technique to be used and injection points for each patient considering the full-face treatment and total injection volume of 3 ml.
4. Monitoring of adverse events during and after the treatment.
5. Taking pictures.

Day 14. Treatment 2.
1. Monitoring of adverse effects.
2. Taking pictures.

Day 21. Control visit.
1. Evaluation of results through numerical satisfaction scales filled in according to doctor and patient responses.
2. Examination of the skin according to the following parameters: texture, thickness, skin type, turgor, flaccidity and general condition.
3. Monitoring of adverse events.

INJECTION MAP:
RRS ® Hyalift® 75

INJECTION DEVICE	30G/32G needle
INJECITON DEPTH	Intradermal
VOLUME PER POINT	0.05 – 0.1 mL
VOLUME PER SIDE	1.5 mL



METHOD

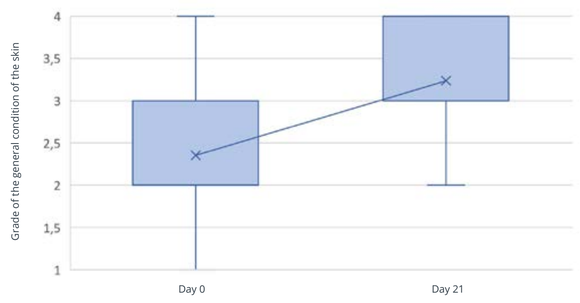
The biorevitalizing solution is applied transdermally, making papules at points of maximum tension in areas of retention ligaments or false ligaments.
The solution is injected with 30 or 32 G needles and luer lock syringes, leaving papules on the skin resting on the retaining ligaments. Two separate sessions are carried out 2 weeks apart, carrying out the control one week after the last application. In each session, 1.5 ml is injected on each side of the face, administering 0.05-0.1 ml of solution per point. For the evaluation of results, numerical scales from 0 to 10 were used for parameters of safety, efficacy, ease of use, local effects of application. Both doctors and patients gave their responses.

SAFETY RESULTS

No allergic reactions or systemic adverse reactions have been detected. The product displays good local tolerability.

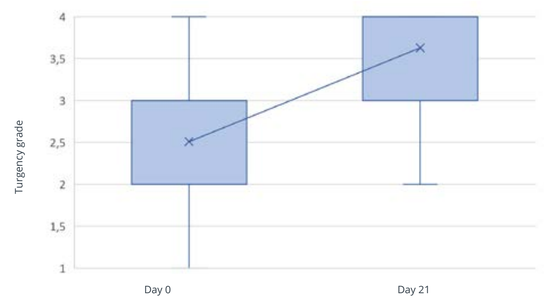
INVESTIGATOR EVALUATION RESULTS

1. Evaluation of the general condition of the skin
Increase in the parameter of the general condition of the skin by the descriptive visual scale, from 2.35 (ranging from 1 to 4) before treatment to a mean grade of 3.24 (ranging from 2 to 4) on day 21 has been observed.



** The grades were distributed as follows: 4 – very good, 3 – good, 2 – moderate, 1 – bad.*

2.Evaluation of skin turgor



Significant increase in the turgor parameter according to the descriptive visual scale, from an average grade of 2.50 (varying from 1 to 4) before treatment to an average grade of 3.62 (with a variation from 2 to 4) on the day 21.

** The grades were distributed as follows: 4 – very good, 3 – good, 2 – moderate, 1 – bad.*

3. Physician satisfaction with skin condition: 100% of investigators rated product efficacy and its adherence to expectation as excellent (82%) and good (18%).

PATIENT ASSESSMENT RESULTS

1. Evaluation of compliance with expectations of the patient: 90% of patients evaluated compliance with their expectations and efficacy of the product as excellent (76%) and good (14%).

2. Patient satisfaction with skin condition: 98% of patients reported skin condition after treatment as excellent (76%) and good (22%).

** The numerical evaluation scale applied to both evaluations: 0-2 – no effect, 3-4 – poor, 5-6 – average, 7-8 – good, 9-10 – excellent.*

CONCLUSIONS

1. HA based mesotherapy (RRS® Hyalift® 75) is indicated for people with an incipient or advanced degree of chrono and photoaging of the skin.
2. The result is the hydration and restructuring of the dermis, improved laxity, thickness, and elasticity as well as improved external signs of skin aging.
3. The application of Sodium Hyaluronate 45 mg/3 ml is an important step prior to treatment with Botulinum Toxin, Fillers or APL to improve the skin condition in patients with aging type III or IV according to the scale of Glogau.
4. In patients with type I or II, it is a treatment that provides satisfactory results by itself, such as the one carried out in this study.

** The author of this poster declares that he has no conflict of interest regarding the product undergoing the study.*

Bibliography: 1. Contet-Audonneau JL, Jeanmaire C, Pauly G. A histological study of human wrinkle structures: com-parison between sun-exposed areas of the face, with or without wrinkles, and sun-protected areas. Br J Dermatol. 1999 Jun;140(6):1038-47. 3. Fallacara A, Baldini E, Manfredini S, Vertuani S. Hyaluronic Acid in the Third Millennium. Polymers (Basel). 2018 jun 25;10(7):701.4. Urdiales-Gálvez F, Delgado NE, Figueiredo V, Lajo-Plaza JV, Mira M, Moreno A, OrtízMartí F, Del Rio-Reyes R, Romero-Álvarez N, Del Cueto SR, Segurado MA. Treatment of Soft Tissue Filler Complications: Expert Consensus Recommendations. Aesthetic Plast Surg. 2018 Apr;42(2):498-510. 5. Becker LC, Bergfeld WF, Belsito DV, Klaassen CD, Marks JG Jr, Shank RC, Slaga TJ; Cosmetic Ingredient Review Expert Panel, Andersen FA. Final report of the safety assessment of hyaluronic acid, potassium hyaluronate, and sodium hyaluronate. Int J Toxicol. 2009 jul-Aug;28(4 Suppl):5-67.